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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/445,205 | 01/07/2000 | JEAN-LUC GALZI | 97AHCNRFLU | 9642 |
| 466 | 7590 | 01/29/2004 | EXAMINER | |
| YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202 | | | SISSON, BRADLEY L | |
| | | | ART UNIT | PAPER NUMBER |

1634

DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/445,205

Applicant(s)

GALZI ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

--The MAILING DATE of this communication appears on the cover sheet with the corresponding address--

THE REPLY FILED 12 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

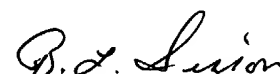
The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: 37 and 38.Claim(s) rejected: 37-52.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____



Bradley L. Sisson
Primary Examiner
Art Unit: 1634

Continuation of 5. does NOT place the application in condition for allowance because: Convincing evidence has not been made of record that shows that claims 1-52 are adequately supported by the specification so as to satisfy the written description requirement of 35 USC 112, first paragraph; and convincing evidence has not been made of record that shows that the claims are fully enabled by the disclosure so as to satisfy the enablement requirement of 35 USC 12, first paragraph. It is noted that the argument advanced in the response of 12 December 2003 redirects attention to the 37 CFR 1.132 Declaration of co-inventor Jean-Luc Galzi, received 09 September 2002. It is noted that the declaration only addresses the aspect of enablement and not the written description rejection of claims 36-52. (Note: At page 4, first line of the Office action of 12 August 2003 claims 1-52 are misidentified. The examiner regrets any confusion that resulted from this typographical error.) Accordingly, the declaration has not been found persuasive towards the withdrawal of the written description rejection of claims 36-52. To the extent that the Declaration addresses the enablement rejection of claims 36-52, the Declaration is silent as to how one can enable that which they do not yet possess, for as presented in paragraph 15 of the Office action of 12 August 2003, claims 36-52 are first rejected on the aspect that one cannot enable that which they do not yet possess.

At page 3, second full paragraph, of the Declaration, declarant asserts: "Variants and fragments can be obtained by random mutagenesis, by site-directed mutagenesis, or by using restriction endonucleases acting on the DNA. Random mutagenesis is obtained by using experimental conditions..." It is noted with particularity that the declaration does not point to where the originally-filed specification provides the detailed guidance of these admittedly "experimental conditions." It is further noted that the invention of claims 49-51 is not directed to a method of making or of using a product. It is directed to a product- a kit, which is comprised of various products. The specification and the declaration are both silent as to how one would select the appropriate components of the kit. At best, the disclosure provides motivation for future researchers to develop methods, using the aforementioned "experimental conditions" which, once identified, could result in the production of products, and which, upon further development, would result in useful products. Neither a review of the originally-filed specification, a review of the Declaration, nor applicant's remarks in their response of 12 December 2003 teach where the requirements of 35 USC 112, first paragraph, have been met. Accordingly, and in the absence of convincing evidence to the contrary, the rejections are maintained.